Attachment 1

Attorney Docket SMI-005.01

Certificate of First Class Mailing

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September 21, 2004 By: Isa Odidi
Date of Signature and Mail Deposit

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant:	Isa Odidi and Amina Odidi	:	Paper No.:
Serial No.	09/166,701	:	Group Art Unit: 1617
Filed:	October 5, 1998	:	Examiner: Webman, Edward J.
For:	**Controlled Release Pharmaceutical Delivery Device and Process For Preparation Thereof**		

DECLARATION UNDER 37 C.F.R. 1.132

Box Fee Amendment
Commissioner for Patents
Washington, DC 20231

Isa Odidi and Amina Odidi declare that:

1. They are co-inventors of and are familiar with the present U.S. Patent Application Serial No. 09/166,701, and they are familiar with the Official Actions issued in the present application and the reference cited by the Examiner; U.S. Patent No. 4,610,870 to Jain *et al.*

2. The controlled release pharmaceutical device and the pharmaceutical composition of the present invention comprise, amongst other components, hydroxyethylcellulose and hydroxypropylmethyl cellulose.

3. U.S. Patent No. 4,610,870 to Jain *et al.* is directed to a controlled release pharmaceutical formulation containing a core portion. The core includes a medicament and a hydrocolloid gelling agent. The hydrocolloid may comprise cellulose polymers which are cellulose ethers such as methyl cellulose, cellulose alkyl hydroxylates such as

hydroxypropylmethyl cellulose, hydroxypropylcellulose, hydroxymethylcellulose or hydroxyethylcellulose.

4. In order to demonstrate that cellulose derivatives are not interchangeable with respect to the present invention, data is provided in Tables 1 and 2 for hydroxypropylmethyl cellulose (HPMC), ethylcellulose (EC), and hydroxyethylcellulose (HEC).

Table 1 Formulation of Model Drug using Different Cellulose Derivatives

Formulation	HPMC 15%	HEC 15%	EC 15%
Model Drug	50%	50%	50%
HPMC	15%	0%	0%
HEC	0%	15%	0%
EC	0%	0%	15%
Lactose	44%	44%	44%
Magnesium Stearate	1%	1%	1%

Table 2 Results from Dissolution studies of the Model Formulations

Time	HPMC 15%	HEC 15%	EC 15%
0	0	0	0
1	16.9	60	88.1
2	25	68	88.2
4	43	75.6	88.3
5	50	78.4	88.4
6	53.4	80	88.5
7	63.3	83.5	88.6
8	66.5	83.2	88.6
10	78.4	88.8	90
11	80.4	87.5	90
12	81.2	84.7	90
13	89.7	90	90
14	92	90	90

5. The amount of drug released in 1 hour is 17% for HPMC, 60% for HEC and 88% for EC. It was also observed that EC tablets broke up in 30 minutes. The time taken for 70% of the drug (i.e., $T_{70\%}$) to be released was about 9 hours for HPMC, 4 hours for HEC and 30 minutes for EC. These results clearly indicate that HPMC, HEC and EC are not interchangeable.

6. These results show that the release rates of the drug depends on the cellulose polymer used. Therefore, since these tests show that cellulosic polymers listed in U.S. Patent No. 4,610,870 to Jain *et al.* are not equivalent in combination with the present invention, one skilled in the art would not assume equivalency of the listed cellulose polymers in combination with the present invention.

7. Isa Odidi and Amina Odidi further declare that all statements made herein of his/her own knowledge are true and that all statements made on information and

belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

4 November ,2003

Isa Odidi

November 4, 2003

Amina Odidi

Attachment 2

Attorney Docket SMI-005.01

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September 21, 2004 By: Marina Daniel
Date of Signature and Mail Deposit

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2. The controlled release pharmaceutical device and the pharmaceutical composition of the present invention comprise, amongst other components, hydroxyethylcellulose (HEC) and hydroxypropylmethyl cellulose (HPMC).

3. In order to demonstrate that hydroxyethylcellulose (HEC) and hydroxypropylcellulose (HPC) are not interchangeable when each are used with

hydroxypropylmethyl cellulose (HPMC), data is provided in Tables 1 and 2 and in Figure 1 for the HPC/HPMC combination compared to the HEC/HPMC combination.

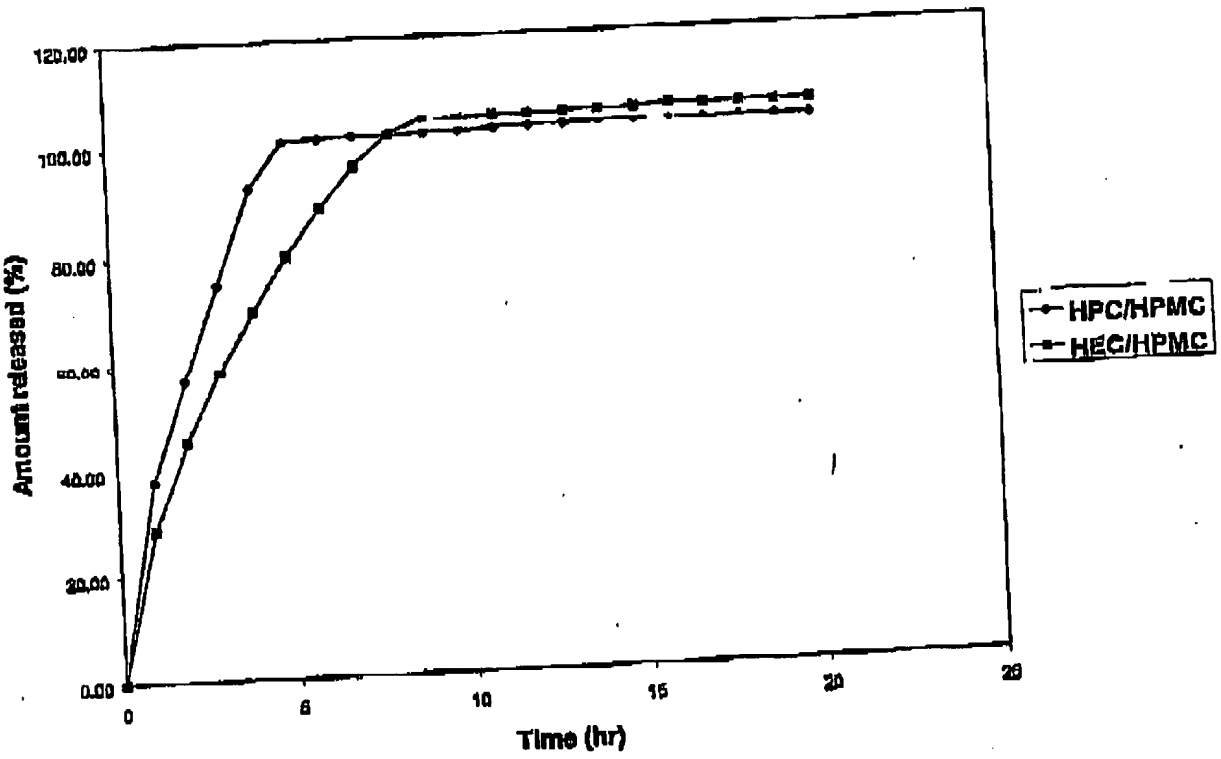
Table 1 Formulation of Model Drug using the Combination of HPC/HPMC vs. HEC/HPMC

Formulation	7.5% HPC and 7.5% HPMC	7.5% HEC and 7.5% HPMC
Model Drug	40%	40%
HPMC	7.5%	7.5%
HPC	7.5%	0%
HEC	0%	7.5%
Lactose	44%	44%
Magnesium Stearate	1%	1%

Table 2 Results from Dissolution studies of the Model Formulations

Time	7.5% HPC and 7.5% HPMC	7.5% HEC and 7.5% HPMC
0	0.00	0.00
1	38.03	28.71
2	56.72	45.27
3	74.81	58.44
4	92.49	69.71
5	100.67	79.9
6	100.97	88.46
7	101.09	95.75
8	101.09	101.33
9	101.39	104.77
10	101.50	104.59
11	101.86	104.71
12	102.10	104.89
13	102.27	105.07
14	102.45	105.18
15	102.51	105.30
16	102.69	105.66
17	102.81	105.66
18	102.87	105.66
19	102.93	105.66
20	102.93	105.66

Figure 1 Dissolution Profiles of Model Formulations



4. The results shown in Table 2 and Figure 1 show significant differences between the release profiles of the two formulations. The amount of drug released in 1 hour is 38% for the HPC/HPMC combination, while the amount of drug released in 1 hour is only 28% for the HEC/HPMC combination. The difference between the two combinations increases with time. For example, the amount of drug released in 4 hours is greater than 90% for the HPC/HPMC combination, while the amount of drug released in 4 hours is less than 70% for the HEC/HPMC combination. Furthermore, it takes 5 hours to release 100% of the drug for the HPC/HPMC combination, while it takes 8 hours before 100% of the drug is released for the HEC/HPMC combination.

5. These results show significant differences in the effect of drug release and availability of the two formulations and clearly indicate that HEC and HPC are not interchangeable when used in combination with HPMC.

6. The differences between the two formulations can impact the decision as to how often a product ought to be taken daily in order to be effective, which also impacts on patient compliance and wellness. These differences also impact adverse effects or safety especially for high potency drugs with low therapeutic indices.

7. Isa Odidi and Amina Odidi further declare that all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

June 8 2004

Isa Odidi

June 8 2004

Amina Odidi